

COPY OF PAPERS
ORIGINALLY FILED

Dkt. 54205-B/JPW/AJM/HML

DECLARATION AND POWER OF ATTORNEY

As a below-named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

METHODS FOR PREDICTING PREGNANCY OUTCOME IN A SUBJECT BY hCG ASSAY

the specification of which:
(check one)

_____ is attached hereto.

X was filed on May 13, 1999 as

Application Serial No. 09/311,428

and was amended May 13, 1999; November 15, 2000; July 17, 2001
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 (a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International Application which designated at least one country other than the United States, listed below. I have also identified below any foreign application for patent or inventor's certificate, or PCT International Application having a filing date before that of the earliest application from which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
Number	Country	Filing Date	Yes	No
PCT/US99/02289	PCT	February 3, 1999	X	

Declaration and Power of Attorney

Page 2

I hereby claim the benefit under Title 35, United States Code, Section 119(e) of any United States provisional application(s) listed below:

<u>Provisional Application No.</u>	<u>Filing Date</u>	<u>Status</u>
<u>N/A</u>		

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States Application(s), or Section 365(c) of any PCT International Application(s) designating the United States listed below. Insofar as this application discloses and claims subject matter in addition to that disclosed in any such prior Application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56, which became available between the filing date(s) of such prior Application(s) and the national or PCT international filing date of this application:

<u>Application Serial No.</u>	<u>Filing Date</u>	<u>Status</u>
<u>09/017,976</u>	<u>February 3, 1998</u>	<u>Pending</u>
<u>PCT/US99/02289</u>	<u>February 3, 1999</u>	<u>Pending</u>

And I hereby appoint

John P. White (Reg. No. 28,678); Christopher C. Dunham (Reg. No. 22,031); Norman H. Zivin (Reg. No. 25,385); Jay H. Maioli (Reg. No. 27,213); William E. Pelton (Reg. No. 25,702); Robert D. Katz (Reg. No. 30,141); Peter J. Phillips (Reg. No. 29,691); Wendy E. Miller (Reg. No. 35,615); Richard S. Milner (Reg. No. 33,970); Robert T. Maldonado (Reg. No. 38,232); Paul Teng (Reg. No. 40,837); Richard F. Jaworski (Reg. No. 33,515); Pedro C. Fernandez (Reg. No. 41,741); Gary J. Gershik (Reg. No. 39,992); Spencer H. Schneider (Reg. No. 45,923); Alan J. Morrison (Reg. No. 37,399); Alan D. Miller (Reg. No. 42,889); and Frank Bruno (Reg. No. 46,583)

and each of them, all c/o Cooper & Dunham LLP, 1185 Avenue of the Americas, New York, New York 10036, my attorneys, each with full power of substitution and revocation, to prosecute this application, to make alterations and amendments therein, to receive the patent, to transact all business in the Patent and Trademark Office connected therewith and to file any International Applications which are based thereon under the provisions of the Patent Cooperation Treaty.

Please address all communications, and direct all telephone calls, regarding this application to:

John P. White Reg. No. 28,678
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
Tel. (212) 278-0400

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first joint inventor John O' Connor
Inventor's signature John O'Connor
Citizenship U.S.A. Date of signature 3/6/02
Residence 781 Pelham Road, Apt. 1A, New Rochelle, New York 10850, U.S.A.
Post Office Address same as above

Full name of joint inventor (if any) Steven Birken
Inventor's signature Steven Birken
Citizenship U.S.A. Date of signature 3/6/02
Residence 120 Oneida Avenue, Dumont, New Jersey 07628, U.S.A.
Post Office Address same as above

Full name of joint inventor (if any) Galina Kovalevskaya
Inventor's signature Galina Kovalevskaya
Citizenship Russia Date of signature 03/06/02
Residence 629 Kappock Street, Apt. 7H, Bronx, New York, 10463, U.S.A.
Post Office Address same as above

Applicants: John O'Connor et al.
Serial No.: 09/311,428
Filed: May 13, 1999
Page 6

REMARKS

Claims 81-91 are pending. Claim 83 has been canceled. Claims 81 and 82 have been amended. Applicants submit that these amendments raise no issue of new matter. Thus, claims 81, 82, and 84-91 will be pending and under examination upon entry of this Amendment.

Examiner Interview

Applicants thank Examiner Cook for her time and consideration during the March 30, 2004 telephonic interview with Dr. Muriel Liberto of the undersigned attorney's office and on the undersigned attorney's behalf. During the interview, it was agreed that the pending claims, as amended herein, would be allowable. Accordingly, allowance is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Supplemental Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this
correspondence is being transmitted
via facsimile on this date to:

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Alan J. Morrison
Reg. No. 37,399

3/31/04
Date

John P. White
Registration No. 28,678
Alan J. Morrison
Registration No. 37,399
Attorneys for Applicants
Cooper & Dunham, LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

Applicant or Patentee: John O'Connor, et al. Attorney's 3
Serial or Patent No.: Not Yet Known Docket No 54205-B/JPW
Filed or Issued: Herewith /JSG
Title of Invention or Patent: METHODS FOR PREDICTING PREGNANCY OUTCOME IN A
SUBJECT BY hCG ASSAY



VERIFIED STATEMENT (DECLARATION) CLAIMING
SMALL ENTITY STATUS UNDER 37 C.F.R. §1.9(f)
AND §1.27(d) - NONPROFIT ORGANIZATION

I hereby declare that I am an official empowered to act on behalf of the nonprofit organization identified below:

Name of Organization: The Trustees of Columbia University in the City of New York

Address of Organization: 110 Low Memorial Library, West 116th & Broadway,
New York, New York 10027

TYPE OF ORGANIZATION:

☒ UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION
☐ TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE 26 U.S.C. §§501(a) and 501(c)(3)
☐ NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA
NAME OF STATE: _____
CITATION OF STATUTE: _____
☐ WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE 26 U.S.C. §§501(a) and 501(c)(3) IF LOCATED IN THE UNITED STATES OF AMERICA
☐ WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA
NAME OF STATE: _____
CITATION OF STATUTE: _____

I hereby declare that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 C.F.R. §1.9(e)* for purposes of paying reduced fees under 35 U.S.C. §41(a) and 41(b), with regard to the invention entitled METHODS FOR PREDICTING PREGNANCY OUTCOME IN A SUBJECT BY hCG ASSAY

by inventor(s) John O'Connor, et al.

described in:

☒ the specification filed herewith
☐ application serial no. _____ filed _____
☐ patent no. _____ issued _____

I hereby declare that rights under contract or law have been conveyed to and remain with the nonprofit organization with regard to the above identified invention.

If the rights held by the nonprofit organization are not exclusive each individual, concern, or organization known to have rights to the invention is listed below^a and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 C.F.R. §1.9(d)* or a nonprofit organization under 37 C.F.R. 1.9(e)*

^a NOTE: Separate verified statements are required from each person, concern, or organization having rights to the invention averring to their status as small entities. 37 C.F.R. §1.27.

Name: N/A

Address: _____

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

*See Reverse

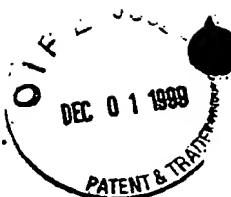
Small Entity Nonprofit:

Page -1-

Applicants: John O'Connor, et al.

U.S. Serial No.: Not Yet Known

Filed: Herewith



I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. 37 C.F.R. §1.28(b)*.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing: Mr. Jack M. Granowitz

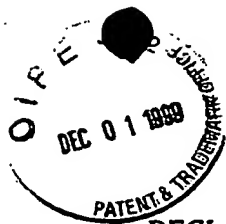
Title In Organization: Executive Director, Columbia Innovation Enterprise

Address: Amsterdam & 120th Street - Suite 363 New York, New York 10027

Signature: *Jack M. Granowitz*

Date Of Signature: May 14, 1999

*See Reverse

**DECLARATION AND POWER OF ATTORNEY**

As a below-named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

METHODS FOR PREDICTING PREGNANCY OUTCOME IN A SUBJECT BY hcG ASSAY

*the specification of which:
(check one)*

 is attached hereto.

 X *was filed on* May 13, 1999 *as*

Application Serial No. 09/311,428

and was amended _____ *(if applicable)*

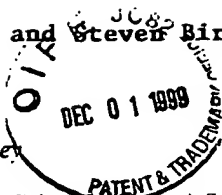
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Prior Foreign Application(s)			Priority Claimed	
<u>Number</u>	<u>Country</u>	<u>Filing Date</u>	<u>Yes</u>	<u>No</u>
PCT/US99/02289	PCT	February 3, 1999	X	
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

Applicants: John O'Connor and Steven Birken
Serial No.: 09/311,428
Filed: May 13, 1999



Declaration and Power of Attorney

Page 2

I hereby claim the benefit under Title 35, United States Code, Section 119(e) of any United States provisional application(s) listed below:

<u>Provisional Application No.</u>	<u>Filing Date</u>	<u>Status</u>
N/A		

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States Application(s), or Section 365(c) of any PCT International Application(s) designating the United States listed below. Insofar as this application discloses and claims subject matter in addition to that disclosed in any such prior Application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56 which became available between the filing date(s) of such prior Application(s) and the national or PCT international filing date of this application:

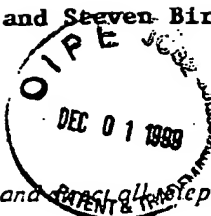
<u>Application Serial No.</u>	<u>Filing Date</u>	<u>Status</u>
09/017,976	February 3, 1999	Pending
PCT/US99/02289	February 3, 1999	Pending

And I hereby appoint

John P. White (Reg. No. 28,678); Christopher C. Dunham (Reg. No. 22,031); Norman H. Zivin (Reg. No. 25,385); Jay H. Maioli (Reg. No. 27,213); William E. Pelton (Reg. No. 25,702); Robert D. Katz (Reg. No. 30,141); Peter J. Phillips (Reg. No. 29,691); Wendy E. Miller (Reg. No. 35,615); Richard S. Milner (Reg. No. 33,970); Albert Wai-Kit Chan (Reg. No. 36,479); Robert T. Maldonado (Reg. No. 38,232); Paul Teng (Reg. No. 40,837); Gary J. Gershik (Reg. No. 39,992); Richard F. Jaworski (Reg. No. 33,515); Elizabeth M. Wieckowski (Reg. No. 42,226); and Pedro C. Fernandez (Reg. No. 41,741)

and each of them, all c/o Cooper & Dunham LLP, 1185 Avenue of the Americas, New York, New York 10036, my attorneys, each with full power of substitution and revocation, to prosecute this application, to make alterations and amendments therein, to receive the patent, to transact all business in the Patent and Trademark Office connected therewith and to file any International Applications which are based thereon under the provisions of the Patent Cooperation Treaty.

Applicants: John O'Connor and Steven Birken
Serial No.: 09/311,428
Filed: May 13, 1999



Declaration and Power of Attorney

Page 3

Please address all communications, and accept all telephone calls, regarding this application to:

John P. White _____ Reg. No. 28,678

Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
Tel. (212) 278-0400

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or
first joint inventor

John O'Connor

Inventor's signature

Citizenship U.S.A.

Date of signature

10/1/99

Residence 781 Pelham Road, Apt. 1A, New Rochelle, New York 10850, U.S.A.

Post Office Address same as above

Full name of joint
inventor (if any)

Steven Birken

Inventor's signature

Citizenship U.S.A.

Date of signature

10/1/99

Residence 120 Oneida Avenue, Dumont, New Jersey 07628, U.S.A.

Post Office Address same as above



DECLARATION AND POWER OF ATTORNEY

As a below-named inventor, I hereby declare that:

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the specification of which:
(check one)

_____ is attached hereto.

☒ was filed on May 13, 1999 as

Application Serial No. 09/311,428

and was amended _____
(if applicable)

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Prior Foreign Application(s)			Priority Claimed	
Number	Country	Filing Date	Yes	No
PCT/US99/02289	PCT	February 3, 1999	<input checked="" type="checkbox"/>	<input type="checkbox"/>
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

Applicants: John C. White and Steven Birken
Serial No.: 09/311,428
Filed: May 13, 1999

Declaration and Power of Attorney

Page 2

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<u>Provisional Application No.</u>	<u>Filing Date</u>	<u>Status</u>
<u>N/A</u>	<u></u>	<u></u>
<u></u>	<u></u>	<u></u>
<u></u>	<u></u>	<u></u>
<u></u>	<u></u>	<u></u>
<u></u>	<u></u>	<u></u>

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<u>Application Serial No.</u>	<u>Filing Date</u>	<u>Status</u>
<u>09/017,976</u>	<u>February 3, 1999</u>	<u>Pending</u>
<u>PCT/US99/02289</u>	<u>February 3, 1999</u>	<u>Pending</u>
<u></u>	<u></u>	<u></u>
<u></u>	<u></u>	<u></u>
<u></u>	<u></u>	<u></u>
<u></u>	<u></u>	<u></u>

And I hereby appoint

John P. White (Reg. No. 28,678); Christopher C. Dunham (Reg. No. 22,031); Norman H. Zivin (Reg. No. 25,385); Jay H. Maioli (Reg. No. 27,213); William E. Pelton (Reg. No. 25,702); Robert D. Katz (Reg. No. 30,141); Peter J. Phillips (Reg. No. 29,691); Wendy E. Miller (Reg. No. 35,615); Richard S. Milner (Reg. No. 33,970); Albert Wai-Kit Chan (Reg. No. 36,479); Robert T. Maldonado (Reg. No. 38,232); Paul Teng (Reg. No. 40,837); Gary J. Gershik (Reg. No. 39,992); Richard F. Jaworski (Reg. No. 33,515); Elizabeth M. Wieckowski (Reg. No. 42,226); and Pedro C. Fernández (Reg. No. 41,741)

and each of them, all c/o Cooper & Dunham LLP, 1185 Avenue of the Americas, New York, New York 10036, my attorneys, each with full power of substitution and revocation, to prosecute this application, to make alterations and amendments therein, to receive the patent, to transact all business in the Patent and Trademark Office connected therewith and to file any International Applications which are based thereon under the provisions of the Patent Cooperation Treaty.

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Full name of sole or

first joint inventor John O'Connor

Inventor's signature John O'Connor

Citizenship U.S.A.

Date of signature 10/1/99

Residence 781 Pelham Road, Apt. 1A, New Rochelle, New York 10850, U.S.A.

Post Office Address same as above

Full name of joint

inventor (if any) Steven Birken

Inventor's signature Steven Birken

Citizenship U.S.A.

Date of signature 10/1/99

Residence 120 Oneida Avenue, Dumont, New Jersey 07628, U.S.A.

Post Office Address same as above

COOPER & DUNHAM LLP
1185 Avenue of the Americas, New York, NY 10036

FACSIMILE TRANSMISSION
Telephone No.: 212-278-0400 / Facsimile No.: 212-391-0525

PLEASE DELIVER THE FOLLOWING PAGES

TO : Examiner Lisa Cook
COMPANY : United States Patent and Trademark Office
FAX NO. : 1-571-273-0816
FROM : Naresh Sritharan, Esq.
RE : 0575/54205-B/JPW/AJM/NS

TOTAL NUMBER OF PAGES, INCLUDING COVER PAGE: **21**

DATE : February 23, 2005

X CONFIDENTIAL

X URGENT

If this facsimile message has reached you in error, please notify us by collect telephone and return it by the Postal Service, as it may contain attorney privileged and confidential information.

MESSAGE:

Further to our telephone conference of today, I transmit herewith a copy of a Request to Correct Inventorship Under 37 C.F.R. §1.48(a) in connection with John O' Connor et al., METHODS FOR PREDICTING PREGNANCY OUTCOME IN A SUBJECT BY HCG ASSAY, U.S. Serial No. 09/311,428, filed May 13, 1999, including a Declaration Under 37 C.F.R. §1.48(a)(2) (**Exhibit A**); signed Declaration and Power of Attorney (**Exhibit B**); Written Consent of Assignee (**Exhibit C**); a copy of a recorded assignment from John O' Connor and Steven Birken to The Trustees of Columbia University in the City of New York (**Exhibit D**); and a Certificate of Mailing dated September 25, 2001.

IF YOU DO NOT RECEIVE ALL OF THE PAGES, PLEASE CALL (212) 278-0400.

FILE

Applicant John O'Connor et al.
Client Columbia- 0575 File No. 54205-B Atty. JPW/SHS/MVM
Date September 25, 2001

Kindly acknowledge receipt of the accompanying

Request to Correct Inventorship Under 37 C.F.R. §1.48(a) in connection with John O'Connor et al., METHODS FOR PREDICTING PREGNANCY OUTCOME IN A SUBJECT BY HCG ASSAY, U.S. Serial No. 09/311,428, filed May 13, 1999, including Declaration Under 37 C.F.R. §1.48(a)(2) (Exhibit A), signed Declaration and Power of Attorney (Exhibit B), Written Consent of Assignee (Exhibit C), a copy of a recorded Assignment from John O'Connor and Steven Birken to The Trustees of Columbia University in the City of New York (Exhibit D) and a Certificate of Mailing dated September 25, 2001.

by placing your receiving date stamp hereon and returning to us.

Applicant John O'Connor et al.
Client Columbia- 0575 File No. 54205-B Atty. JPW/SHS/MVM
Date September 25, 2001

Kindly acknowledge receipt of the accompanying

Request to Correct Inventorship Under 37 C.F.R. §1.48(a) in connection with John O'Connor et al., METHODS FOR PREDICTING PREGNANCY OUTCOME IN A SUBJECT BY HCG ASSAY, U.S. Serial No. 09/311,428, filed May 13, 1999, including Declaration Under 37 C.F.R. §1.48(a)(2) (Exhibit A), signed Declaration and Power of Attorney (Exhibit B), Written Consent of Assignee (Exhibit C), a copy of a recorded Assignment from John O'Connor and Steven Birken to The Trustees of Columbia University in the City of New York (Exhibit D) and a Certificate of Mailing dated September 25, 2001.

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Dkt. 54205-B/JPW/SHS/MVM

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: John O'Connor et al.

Serial No.: 09/311,428

Group Art Unit: 1641

Filed : May 13, 1999

Examiner: L. Cook

For : METHODS FOR PREDICTING PREGNANCY OUTCOME IN A
SUBJECT BY hCG ASSAY1185 Avenue of the Americas
New York, New York 10036
September 25, 2001Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

REQUEST TO CORRECT
INVENTORSHIP UNDER 37 C.F.R. §1.48(a)

This Request To Correct Inventorship Under 37 C.F.R. §1.48(a) is submitted in order to correct the inventorship in the above-identified patent application ("subject application").

Applicants hereby request under 37 C.F.R. §1.48(a) that inventorship of the subject application be corrected. Applicants have determined that the inventorship of the claimed invention is incorrect because an actual inventor was inadvertently not named as an inventor.

The currently named inventors in the subject application are the following: John O'Connor and Steven Birken.

Please add Galina Kovalevskaya as an inventor of the claimed invention. A Declaration Under 37 C.F.R. §1.48(a)(2) executed by Galina Kovalevskaya which states that the error in inventorship occurred without deceptive intent is attached hereto as Exhibit A.

Upon correction, the inventors in the subject application will be John O'Connor, Steven Birken and Galina Kovalevskaya.

Applicants : John O'Connor et al.
Serial No. : 09/311,428
Filed : May 13, 1999
Page 2

Applicants attach hereto as Exhibit B a Declaration executed by John O'Connor, Steven Birken and Galina Kovalevskaya as required by 37 C.F.R. §1.63.

Applicants also respectfully request that the United States Patent and Trademark Office issue a corrected filing receipt upon the entry of this amendment.

In addition, the currently named inventors of the invention claimed in the subject application, i.e., John O'Connor and Steven Birken, assigned their rights in the subject application to The Trustees of Columbia University in the City of New York. The Assignment was recorded on December 1, 1999 in the United States Patent and Trademark Office at reel number 010420, frames 0364-0366. A Written Consent Of The Assignee to add Galina Kovalevskaya as an inventor in the subject application is attached hereto as Exhibit C.

The Assignee's ownership is established, under 37 C.F.R. §3.73, by submission of a true copy of the recorded Assignment, which is attached hereto as Exhibit D.

Applicants are concurrently filing an Assignment of rights in the subject invention and patent application from Galina Kovalevskaya to The Trustees of Columbia University in the City of New York in which Galina Kovalevskaya will assign her entire right, title and interest to any and all inventions disclosed and/or claimed in the subject application. Accordingly, the Assignee will still own the entire right, title and interest to any and all inventions disclosed and/or claimed in the subject application.

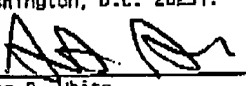
Applicants hereby authorize the United States Patent and Trademark Office to charge the amount of \$130.00 as set forth in 37 C.F.R. §1.17(i) to cover the processing fee.

Applicants : John O'Connor et al.
Serial No. : 09/311,428
Filed : May 13, 1999
Page 3

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone either of them at the number provided below.

No fee, other than the \$130.00 processing fee is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.	
	9-25-01
John P. White	Date
Reg. No. 28,678	
Spencer H. Schneider	
Reg. No. 45,923	



John P. White
Registration No. 28,678
Spencer H. Schneider
Registration No. 45,923
Attorneys for Applicant(s)
Cooper & Dunham, LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

EXHIBIT A

Dkt. 54205-B/JPW/SHS/MVM

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: John O'Connor et. al.
Serial No.: 09/311,428 Group Art Unit: 1641
Filed : May 13, 1999 Examiner: L. Cook
For : METHODS FOR PREDICTING PREGNANCY OUTCOME IN A
SUBJECT BY HCG ASSAY

1185 Avenue of the Americas
New York, New York 10036

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

DECLARATION UNDER 37 C.F.R. §1.48(a)(2)

I, Galina Kovalevskaya, hereby declare that:

1. I am one of the inventors of the claimed invention in the above-identified patent application ("subject application").
2. I understand the currently named inventors of the claimed invention in the subject application are John O'Connor and Steven Birken.
3. The invention described and claimed in the subject application was conceived by John O'Connor, Steven Birken and me.
4. Accordingly, the actual inventors of the claimed invention in the subject application are: John O'Connor, Steven Birken and Galina Kovalevskaya.
5. The error in inventorship occurred without any deceptive intention on my part.

Applicants: John O'Connor et al.
Serial No.: 09/311,428
Filed: May 13, 1999
Page 2

I hereby declare that all statements made herein of my own knowledge are true and that all statements made herein on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the subject application or any patent issuing thereon.

Dated: August 29, 2001 G. Kovalevskaya
Galina Kovalevskaya

EXHIBIT B

Dkt. 54205-B/JPW/SBS/MVM

DECLARATION AND POWER OF ATTORNEY

As a below-named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

METHODS FOR PREDICTING PREGNANCY OUTCOME IN A SUBJECT BY hCG ASSAY

the specification of which:
(check one)

 is attached hereto.

X was filed on May 13, 1999 as

Application Serial No. 09/311,428

and was amended May 13, 1999; November 15, 2000; July 17, 2001
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 (a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International Application which designated at least one country other than the United States, listed below. I have also identified below any foreign application for patent or inventor's certificate, or PCT International Application having a filing date before that of the earliest application from which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
Number	Country	Filing Date	Yes	No
PCT/US99/02289	PCT	February 3, 1999	<u>X</u>	<u> </u>
<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
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<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>

Page 2

Declaration and Power of Attorney

I hereby claim the benefit under Title 35, United States Code, Section 119(e) of any United States provisional application(s) listed below:

<u>Provisional Application No.</u>	<u>Filing Date</u>	<u>Status</u>
N/A		

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States Application(s), or Section 365(c) of any PCT International Application(s) designating the United States listed below. Insofar as this application discloses and claims subject matter in addition to that disclosed in any such prior Application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56, which became available between the filing date(s) of such prior Application(s) and the national or PCT international filing date of this application:

<u>Application Serial No.</u>	<u>Filing Date</u>	<u>Status</u>
09/017,976	February 3, 1999	Pending
PCT/US99/02289	February 3, 1999	Pending

And I hereby appoint

John P. White (Reg. No. 28,768); Christopher C. Dunham (Reg. No. 22,031); Norman H. Zivin (Reg. No. 25,385); Jay H. Maioli (Reg. No. 27,213); William E. Pelton (Reg. No. 25,702); Robert D. Katz (Reg. No. 30,141); Peter J. Phillips (Reg. No. 29,691); Wendy E. Miller (Reg. No. 35,615); Richard S. Milner (Reg. No. 33,970); Robert T. Maldonado (Reg. No. 38,232); Paul Teng (Reg. No. 40,837); Richard F. Jaworski (Reg. No. 33,515); Pedro C. Fernandez (Reg. No. 41,741); Gary J. Gershik (Reg. No. 39,992); Jane M. Love (Reg. No. 42,812); Spencer H. Schneider (Reg. No. 45,923); Alan J. Morrison (Reg. No. 37,399); Alan D. Miller (Reg. No. 42,889); Christopher M. Ries (Reg. No. 45,799) and Frank Bruno (Reg. No. 46,583)

and each of them, all c/o Cooper & Dunham LLP, 1185 Avenue of the Americas, New York, New York 10036, my attorneys, each with full power of substitution and revocation, to prosecute this application, to make alterations and amendments therein, to receive the patent, to transact all business in the Patent and Trademark Office connected therewith and to file any International Applications which are based thereon under the provisions of the Patent Cooperation Treaty.

Page 3

Declaration and Power of Attorney

Please address all communications, and direct all telephone calls, regarding this application to:

John P. White Reg. No. 28,678

Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
Tel. (212) 278-0400

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first joint inventor

John O' Connor

Inventor's signature

John O'Connor

Citizenship U.S.A.

Date of signature

8/29/01

Residence 781 Pelham Road, Apt. 1A, New Rochelle, New York 10850, U.S.A.

Post Office Address same as above

Full name of joint inventor (if any)

Steven Birken

Inventor's signature

Steven Birken

Citizenship U.S.A.

Date of signature

9/4/01

Residence 120 Oneida Avenue, Dumont, New Jersey 07628, U.S.A.

Post Office Address same as above

Full name of joint inventor (if any)

Galina Kovalevskaya

Inventor's signature

G. Kovalevskaya

Citizenship Russia

Date of signature

08/29/2001

Residence 629 Kappock Street, Apt. 7B, Bronx, New York, 10463, U.S.A.

Post Office Address same as above

EXHIBIT C

Dkt. 54205-B/JPW/SHS/MVM

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: John O'Connor et al.
Serial No.: 09/311,428 Group Art Unit: 1641
Filed : May 13, 1999 Examiner: L. Cook
For : METHODS FOR PREDICTING PREGNANCY OUTCOME IN A
SUBJECT BY hCG ASSAY

1185 Avenue of the Americas
New York, New York 10036

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

WRITTEN CONSENT OF ASSIGNEE

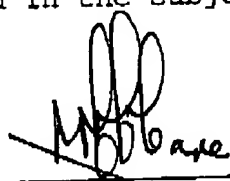
I, Michael J. Cleare, hereby declare that:

1. I understand the currently named inventors of the claimed invention in the subject application are John O'Connor and Steven Birken.
2. John O'Connor and Steven Birken assigned their rights in the subject application to The Trustees of Columbia University in the City of New York ("the Assignee"). The Assignment was recorded on December 1, 1999 in the United States Patent and Trademark Office at reel number 010420, frames 0364-0366.
3. I also understand that the invention described and claimed in the subject application was conceived by John O'Connor, Steven Birken and Galina Kovalevskaya. Therefore, the inventors of the claimed invention in the subject application are: John O'Connor, Steven Birken and Galina Kovalevskaya.
4. I am an official authorized to act on behalf of the Assignee.

Applicants: John O'Connor et al.
Serial No.: 09/311,428
Filed: May 13, 1999
Page 2

5. The Assignee hereby consents to the addition of Galina Kovalevskaya as an inventor in the subject application.
6. In addition, it is the Assignee's understanding that Galina Kovalevskaya will assign her entire right, title and interest to any and all inventions disclosed and/or claimed in the subject application. Accordingly, the Assignee will still own the entire right, title and interest to any and all inventions disclosed and/or claimed in the subject application.

Dated: 08/20/01



Michael J. Cleare, Ph.D.
Executive Director
Columbia Innovation Enterprise

EXHIBIT D



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

MARCH 03, 2000

PTAS

COOPER & DUNHAM LLP
JOHN P. WHITE, ESQ.
1185 AVENUE OF THE AMERICAS
NEW YORK, NEW YORK 10036



UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 12/01/1999

REEL/FRAME: 010420/0364
NUMBER OF PAGES: 3

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:
O'CONNOR, JOHN

DOC DATE: 10/01/1999

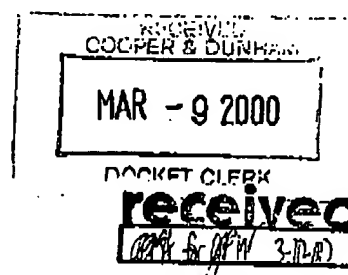
ASSIGNOR:
BIRKEN, STEVEN

DOC DATE: 10/01/1999

ASSIGNEE:
TRUSTEES OF COLUMBIA UNIVERSITY IN
THE CITY OF NEW YORK, THE
WEST 116TH STREET AND BROADWAY
NEW YORK, NEW YORK 10027

SERIAL NUMBER: 09311428
PATENT NUMBER:

FILING DATE: 05/13/1999
ISSUE DATE:



010420/0364 PAGE 2

TARA WASHINGTON, EXAMINER
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

FORM PTO-1595 (Substitute)

(Rev. 8-96) MRD 12-1-99

101218043

U.S. DEPARTMENT OF COMMERCE

Patent and Trademark Office

To the Honorable Commissioner of Patents and Trademarks

Documents or copy thereof.

1. Name of conveying party(ies):

John O'Connor and
Steven Birken

Additional name(s) of conveying party(ies) attached?

☐ Yes ☒ No

3. Nature of Conveyance:

- ☒ Assignment ☐ Merger
☐ Security Agreement ☐ Change of Name
☐ Other _____

Execution Date(s): 10/1/99; 10/1/99

2. Name and address of receiving party(ies):

The Trustees of Columbia University
Name: in the City of New York

Internal Address: _____

Street Address: West 116th Street and Broadway

City/State/Zip: New York, New York 10027

Additional name(s) & address(es) attached? ☐ Yes ☒ No

4. Application number(s) or patent number(s): If this document is being filed together with a new application, the execution date(s) of the application is(are):

A. Patent Application No.(s) 09/311,428

Filed May 13, 1999

B. Patent No.(s) _____

Additional numbers attached? ☐ Yes ☒ No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: John P. White, Esq.

Internal Address: Cooper & Dunham LLP

Street Address: 1185 Avenue of the Americas

City/State/Zip: New York, New York 10036

6. Total number of applications and patents involved: 1

7. Total fee (37 CFR §3.41): \$ 40.00

☐ Enclosed☒ Authorized to be charged to deposit account

8. Deposit account number:

03-3125

DO NOT USE THIS SPACE

9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

John P. White

Name of Person Signing

Reg. No.: 28,678

Signature

November 29, 1999

Date

Total Number of pages including cover sheet, attachments and document: 3

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231.

John P. White
Reg. No. 28,678

Date

OMB No. 0651-0011 (exp. 4/94)

Mail documents to be recorded with required cover sheet information to:
 Commissioner of Patents and Trademarks
 Box Assignments

09314428
00000335 05/21/25
40.00 CH
185:35
01 FC:581

Assignment

In consideration of One Dollar (\$1.00), and other good and valuable considerations, the receipt of which is hereby acknowledged, we, the undersigned,

John O'Connor, residing at 781 Pelham Road, Apt. 1A, New Rochelle,
New York 10850, U.S.A.; and

Steven Birken, residing at 120 Oneida Avenue, Dumont, New Jersey 07628, U.S.A.

Hereby sell, assign and transfer to The Trustees of Columbia University in the
City of New York a corporation of the State of New York

having a place of business at West 116th Street and Broadway
in the County of New York and State of New York, 10027, U.S.A.

its successors, assigns and legal representatives, the entire right, title and interest
for all countries, in and to any and all inventions which are disclosed and claimed,
and any and all inventions which are disclosed but not claimed, in the application for
United States Patent, which has been executed by the undersigned on October 1, 1999 and
October 1, 1999
and is entitled

METHODS FOR PREDICTING PREGNANCY OUTCOME IN A SUBJECT BY hCG ASSAY
(U.S. Serial No. 09/311,428, filed May 13, 1999, a continuation-in-part
application of International Application No. PCT/US99/02289, filed
February 3, 1999, a continuation-in-part of U.S. Serial No. 09/017,976,
filed February 3, 1998)

and in and to said application and all divisional, continuing, substitute, renewal,
reissue, and all other applications for U.S. Letters Patent or other related property
rights in any and all foreign countries which have been or shall be filed on any of
said inventions disclosed in said application; and in and to all original and reissued
patents or related foreign documents which have been or shall be issued on said
inventions;

Authorize and request the Commissioner of Patents of the United States to issue
to said Assignee, the corporation above named, its successors, assigns and legal
representatives, in accordance with this assignment, any and all United States
Letters Patent on said inventions or any of them disclosed in said application;

Applicants: Jo Connor and Steven Birken
 Serial No.: 05 28
 Filed: May 13 99
 Page 2

Agree that said Assignee may apply for and receive foreign Letters Patent or rights of any other kind for said inventions, or any of them; and may claim, in applications for said foreign Letters Patent or other rights, the priority of the aforesaid United States patent application under the provisions of the International Convention of 1883 and later modifications thereof, under the Patent Cooperation Treaty, under the European Patent Convention or under any other available international agreement; and that, when requested, without charge to, but at the expense of, said Assignee, its successors, assigns and legal representatives, to carry out in good faith the intent and purpose of this assignment, the undersigned or the undersigned's executors or administrators will, for the United States and all foreign countries, execute all divisional, continuing, substitute, renewal, reissue, and all other patent applications or other documents on any and all said inventions; execute all rightful oaths, assignments, powers of attorney and other papers; communicate to said Assignee, its successors, assigns and representatives, all facts known and documents available to the undersigned relating to said inventions and the history thereof; testify in all legal proceedings; and generally do everything possible which said Assignee, its successors, assigns or representatives shall consider desirable for aiding in securing, maintaining and enforcing proper patent protection for said inventions and for vesting title to said inventions and all applications for patents or related foreign rights and all patents on said inventions, in said Assignee, its successors, assigns and legal representatives; and

Covenant with said Assignee, its successors, assigns and legal representatives that no assignment, grant, mortgage, license or other agreement affecting the rights and property herein conveyed has been made to others by the undersigned, and that full right to convey the same as herein expressed is possessed by the undersigned.

Date: 10/1/99 19

Witness: Scot G. Hamilton

Scot G. Hamilton

53 Elizabeth Terr

Upper Saddle River NJ 07445

John O'Connor [L.S.]
 John O'Connor

Date: 10/1/99 19

Witness: Scot G. Hamilton

Scot G. Hamilton

53 Elizabeth Terr

Upper Saddle River NJ

Steven Birken [L.S.]
 Steven Birken